CLAIMS

1. A pharmaceutical composition as a solid dosage form comprising desmopressin, or a pharmaceutically acceptable salt thereof, as a therapeutically active ingredient together with a pharmaceutically acceptable excipient, diluent or carrier, or mixture thereof, wherein the pharmaceutical composition is composed of a compressed granulate and contains lubricant in an amount of from 0.05 to less than 0.50 percent by weight of said pharmaceutical composition.

2. A pharmaceutical composition according to claim 1 which contains lubricant in an amount of from 0.10 to less than 0.50 percent by weight of said pharmaceutical composition.

3. A pharmaceutical composition according to claim 2 which contains lubricant in an amount of from 0.15 to 0.45, preferably from 0.20 to 0.40, and more preferably from 0.25 to 0.30, percent by weight of said pharmaceutical composition.

4. A pharmaceutical composition according to any one of claims 1-3 which is compressed of a granulate with an average size of at least 100 µm, preferably in the range of from 100 µm to 2 mm, more preferably in the range of from 100 to 600 µm.

5. A pharmaceutical composition according to claim 4, wherein said granulate has a size distribution where at least 50%, preferably from 50 to 90%, by volume thereof consists of granulate particles with a size of at least 100 µm, preferably in the range of from 100 µm to 2 mm, more preferably in the range of from 100 to 600 µm.

6. A pharmaceutical composition according to any one of claims 1-5, wherein said lubricant is selected from a group consisting of stearic acid, salts or esters of stearic acid, hydrogenated vegetable oils, magnesium oxide, polyethylene glycol, sodium lauryl sulphate and talc, and mixtures thereof.

7. A pharmaceutical composition according to claim 6, wherein said lubricant is selected from magnesium stearate, calcium stearate, zinc stearate, glyceryl palmitostearate and sodium stearyl fumarate, and mixtures thereof.

8. A pharmaceutical composition according to any one of claims 1-7, wherein at least one of said excipient, diluent and carrier is a substance selected from a monosaccharide, disaccharide, oligosaccharide and a polysaccharide.

9. A pharmaceutical composition according to claim 8, wherein the said substance has an average particle size in the range of from 60 to 1 000 μm.

10. A pharmaceutical composition according to claim 9, wherein said average particle size is in the range of from 70 to 500 μm, preferably from 75 to 350 μm, more preferably from 100 to 200 μm, and even more preferably from 120 to 180 μm.

11. A pharmaceutical composition according to any one of claims 8-10, wherein said substance is a disaccharide, preferably lactose, and more preferably lactose-α-monohydrate.

12. A pharmaceutical composition according to any one of claims 8-10, wherein said polysaccharide is a starch, preferably potato starch.

13. A pharmaceutical composition according to any one of claims 8-12, wherein both said disaccharide and polysaccharide are present.

14. A pharmaceutical composition according to claim 13, wherein the weight ratio between said disaccharide and polysaccharide is from 100:1 to 1:100, preferably from 10:1 to 1:10, and more preferably from 2:1 to 1:2.

15. A pharmaceutical composition according to any one of claims 1-14, wherein the total combined amount of said excipient, diluent and carrier is from 5 to 99, preferably from 50 to 99, percent by weight of the pharmaceutical composition.

16. A pharmaceutical composition according to any one of claims 1-15, wherein said solid dosage form is a perorally available tablet that is optionally adapted for oromucosal, preferably buccal and/or sublingual, administration.

17. A pharmaceutical composition according to any one of claims 1-16, which comprises desmopressin acetate in an amount of from 20 to 600 µg per unit of solid dosage form.

18. A pharmaceutical composition according to any one of claims 1-17, wherein each unit of solid dosage form has a hardness of at least 5 kp.

19. A method for the manufacturing of a pharmaceutical composition as a solid dosage form comprising desmopressin, or a pharmaceutically acceptable salt thereof, as a therapeutically active ingredient, wherein said method comprises the steps of:

i) mixing desmopressin and an excipient, diluent or carrier, or mixture thereof, optionally in the presence of a wetting agent;

ii) subjecting the resulting mixture to formation of a granulate, optionally in the presence of a wetting agent, suitable for compression into said solid dosage form;

iii) optionally performing said mixing and/or formation of a granulate in the presence of at least one additive selected from a disintegrating agent, binder, flavoring agent, preservative, colorant and a mixture thereof;

iv) optionally drying said granulate;

v) compressing said granulate into said solid dosage form;

wherein lubricant is introduced so that the resulting pharmaceutical composition contains lubricant in an amount of from 0.05 to less than 0.50 percent by weight of said pharmaceutical composition.

20. A method according to claim 19, wherein the pharmaceutical composition contains lubricant in an amount of from 0.10 to less than 0.50 percent by weight of said pharmaceutical composition.

21. A method according to claim 20, wherein the pharmaceutical composition contains lubricant in an amount of from 0.15 to 0.45, preferably from 0.20 to 0.40, and more preferably from 0.25 to 0.30, percent by weight of said pharmaceutical composition.

22. A method according to any one of claims 19-21, wherein said resulting mixture is subjected to formation of a granulate with an average size of a least 100 µm, preferably in the range of from 100 µm to 2 mm, more preferably in the range of from 100 to 600 µm.

23. A method according to claim 22, wherein said formation of granulate provides a size distribution where at least 50%, preferably from 50 to 90%, by volume of said granulate consists of granulate particles with a size of at least 100 µm, preferably in the range of from 100 µm to 2 mm, more preferably in the range of from 100 to 600 µm.

24. A method according to any one of claims 19-23, wherein said lubricant is selected from a group consisting of stearic acid, salts or esters of stearic acid, hydrogenated vegetable oils, magnesium oxide, polyethylene glycol, sodium lauryl sulphate and talc, and mixtures thereof.

25. A method according to claim 24, wherein said lubricant is selected from magnesium stearate, calcium stearate, glyceryl palmitostearate, sodium stearyl fumarate and zinc stearate, and mixtures thereof.

26. A method according to any one of claims 19-25, wherein at least one of said excipient, diluent and carrier is a substance selected from a monosaccharide, disaccharide, oligosaccharide and a polysaccharide.

27. A method according to claim 26, wherein said substance has an average particle size in the range of from 60 to 1 000 μm.

28. A method according to claim 27, wherein said average particle size is in the range of from 70 to 500 μm, preferably from 75 to 350 μm, more preferably from 100 to 200 μm, and even more preferably from 120 to 180 μm.

29. A method according to any one of claims 26-28, wherein said substance is a disaccharide, preferably lactose, and more preferably lactose-α-monohydrate.

30. A method according to any one of claims 26-28, wherein said polysaccharide is a starch, preferably potato starch.

31. A method according to any one of claims 19-30, wherein said solid dosage form is a perorally available tablet that is optionally adapted for oromucosal, preferably buccal and/or sublingual, administration.

32. A method according to any one of claims 19-31, wherein said steps of mixing and formation of a granulate are performed in a single integrated machinery that is adapted for such a combined process.

33. A method according to any one of claims 19-32, wherein said wetting agent is selected from water and a mixture of water and an alcohol, preferably ethanol.

34. A method according to any one of claims 19-33, wherein both said disaccharide and polysaccharide are present in the mixing step.

35. A method according to claim 34, wherein the weight ratio between said disaccharide and polysaccharide is from 100:1 to 1:100, preferably from 10:1 to 1:10, and more preferably from 2:1 to 1:2.

36. A method according to any one of claims 19-35, wherein the total combined amount of said excipient, diluent and carrier is from 5 to 99, preferably from 50 to 99, percent by weight of the pharmaceutical composition.

37. A method according to any one of claims 19-36, wherein desmopressin acetate is used and mixed with the excipient, diluent or carrier in an amount that provides from 20 to 600 μg of desmopressin acetate per unit of solid dosage form.

38. A method according to any one of claims 19-37, wherein each unit of solid dosage form is compressed to a hardness of at least 5 kp.

39. A pharmaceutical composition as a solid dosage form that is obtainable by a method as defined in any one of claims 19-38.